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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/407.605	09/28/1999	ALLAN M. MILLER	10278/009001	2966
26161	7590	04/06/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/407,605

Applicant(s)

MILLER ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 81-94, 96-108 and 110-112 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 81-89, 91-94, 96, 97, 99-101, 103, 105-108 and 110-112 is/are rejected.
- 7) ☒ Claim(s) 90, 98, 102 and 104 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 81-94, 96-108 and 110-112 are pending.

Applicants' amendment filed September 8, 2003 is acknowledged, and applicants' response has been fully considered. Claims 111 and 112 have been amended, and claims 1-80, 95, 109 and 113-135 have been cancelled. Therefore, claims 81-94, 96-108 and 110-112 are examined.

### ***Sequence Listing***

2. The sequence Listing filed January 8, 2004 is acknowledged, and CRF has been entered.

### **Rejection Withdrawn**

#### ***Claim Rejections-Obviousness Type Double Patenting***

3. The previous rejection of claims 64-79, 111-120, 122-125, 127-130 and 132-135 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending application No. 09/686,497, is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claim, and applicants' response at page 8 in the amendment filed September 8, 2003.

#### ***Claim Rejections - 35 USC § 102***

4. The previous rejection of claims 64, 65, 68-71, 73, 74, 76-79, 113-115 and 119 under 35 U.S.C. 102(a) as anticipated by Coleman *et al.* (WO 98/24922), is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 8 in the amendment filed September 8, 2003.

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5. The previous rejection of claims 64, 65, 68-71, 73, 74, 76-79, 113-115 and 119 under 35 U.S.C. 102(e) as anticipated by Ralston *et al.* (U. S. Patent 6,034,072), is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 8 in the amendment filed September 8, 2003.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 111 and 112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 111 and 112 are indefinite because the claims are dependent from a cancelled claim, claim 64, 69 or 73.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 81-89, 91-94, 96, 97, 99-101, 103, 105-108 and 110 rejected under 35 U.S.C. 103(a) as being unpatentable over Seed *et al.* (U. S. Patent 6,114,148, filed 9/20/1996).

Seed *et al.* teach a synthetic gene encoding a protein such as factor VIII or Factor IX normally expressed in a mammalian cell or other eukaryotic cells, wherein at least one non-preferred or less preferred codon in the normal gene encoding the protein has been replaced by a preferred codon encoding the same amino acid, where the preferred codon is indicated in the highly expressed human genes (column 1, lines 23-57; Table 1); at least 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80% or 90% of the codons in the natural gene are non-preferred codons (column 2, lines 21-23); at least 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80% or 90% of the non-preferred codons in the natural gene are replaced with preferred codons (column 2, lines 28-31; claims 81, 83-85, 87-89, 91-94, 96, 97, 99-101, 103, 105-108 and 110; and the synthetic gene can be a beta domain deleted (BDD) factor VIII (column 2, lines 37-39; Example III; claims 82, 86). Although Seed *et al.* do not specifically disclose the synthetic nucleic acid having a continuous stretch of at least 150 common codons or of 60% of the codons of the synthetic nucleic acid sequence, or at least 98% or more of the codons in the sequence encoding the protein (e.g., factor VIII or factor IX) are common codons, and the protein is at least 90 amino acid residues in length, at the time of invention was made, it would have been obvious to one of ordinary skill in the art that the reference suggests the nucleic acid sequence has the continuous stretch of common codons cited in the claims because the reference indicates at least 90% of the

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non-preferred codons in the natural gene are replaced with preferred codons, which includes all or most of non-preferred codons replaced. Thus, the teaching of the reference results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

8. Claims 90, 98, 102 and 104 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

9. Claims 81-89, 91-94, 96, 97, 99-101, 103, 105-108 and 110-112 are rejected, and claims 90, 98, 102 and 104 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *cmk*  
Patent Examiner

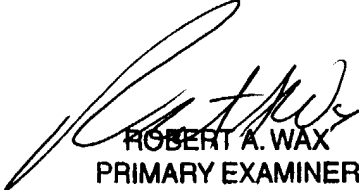
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March 23, 2004



ROBERT A. WAX  
PRIMARY EXAMINER